DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING
Heber M. Wells Building
160 East 300 South
P O Box 146741
Salt Lake City UT 84114-6741
Telephone: (801) 530-6628

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING OF THE DEPARTMENT OF COMMERCE OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF	:	
A&W PHARMACY	:	**NOTICE OF AGENCY ACTION**
TO OPERATE AS A PHARMACY AND TO	:	
DISPENSE CONTROLLED SUBSTANCES	:	
IN THE STATE OF UTAH	:	Case No. DOPL-2019-189

THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING TO A&W Pharmacy ("Respondent"):

The Division of Occupational and Professional Licensing ("the Division") hereby files this notice of agency action. Said action is based on the Division's verified petition, a copy of which is attached hereto and incorporated herein by reference.

The adjudicative proceeding designated herein is to be conducted on a formal basis. It is maintained under the jurisdiction and authority of the Division as set forth in §58-1-401(2). **Within thirty (30) days of the mailing date of this notice, you are required to file a written response with this Division.** The response you file may be helpful to clarify, refine or narrow the facts and violations alleged in the verified petition.

Your written response, and any future pleadings or filings, which are a part of the official file in this proceeding, should be mailed or hand delivered to the following:

Signed originals to:
Division of Occupational
and Professional Licensing
Attn: Disciplinary Files
(by mail): PO Box 146741
Salt Lake City UT 84114-6741
(by hand delivery):
160 East 300 South, 4th floor
Salt Lake City, Utah

A copy to:
Kevin M. McDonough
Assistant Attorney General
Heber M. Wells Building
(by mail): PO Box 140872
Salt Lake City UT 84114-0872
(by hand delivery):
160 East 300 South, 5th floor
Salt Lake City, Utah

You may represent yourself or, at your own expense, be represented by legal counsel at all times while this action is pending. **Your legal counsel shall file an entry of appearance with the Division after being retained to represent you in this proceeding.** Until that entry of appearance is filed, the Division, its counsel, and the presiding officer will communicate directly with you.

The presiding officer for the purpose of conducting this proceeding will be Bruce L. Dibb, Administrative Law Judge, Department of Commerce, who will preside over any evidentiary issues and matters of law or procedure. If you or your attorney may have questions as to the procedures relative to the case, Judge Dibb can be contacted in writing at P O Box 146701, Salt Lake City, UT 84114-6701; by telephone at (801) 530-6706; or by electronic mail at bdibb@utah.gov.

Pursuant to a determination previously made by the Division which generally governs proceedings of this nature, the Division is providing the relevant and nonprivileged contents of its investigative file to you, concurrent with the issuance of this notice.

The Division is also providing its witness and exhibit list to you, concurrent with the issuance of this notice. The witness list identifies each individual the Division expects to present as a witness and includes a brief summary of their testimony at the hearing. The exhibit list identifies each anticipated document which the Division expects to present at the hearing. The Division is also providing a copy of any document to you that has not been otherwise made available to you through the investigative file.

Concurrent with your filing of a written response, you should provide to the Division a copy of any documents you have which relate to this case. Further, you should provide your witness and exhibit list to the Division. The witness list should identify each individual you expect to present as a witness and include a brief summary of their anticipated testimony. The exhibit list should identify each document you expect to present at the hearing.

If you fail to file a response within the 30 days allowed or fail to attend or participate in any scheduled hearing, Judge Dibb may enter a default against you without any further notice to you.

After the issuance of a default order, Judge Dibb will

cancel any prehearing conference or hearing scheduled in the Division's verified petition, conduct any further proceedings necessary to complete the adjudicative proceeding without your participation and determine all issues in the proceeding.

If you are held in default, the maximum administrative sanction consistent with the verified petition may be imposed against you. That sanction in this case is revocation of license and an administrative fine.

Counsel for the Division in this proceeding is Kevin McDonough, Assistant Attorney General, State of Utah. Mr. McDonough may be contacted in writing at P.O. Box 140872, Salt Lake City, UT 84114-0872 or by telephone at (801) 366-0310. **You may, subject to the deadlines established herein, attempt to negotiate a settlement of this proceeding by contacting counsel for the Division.**

Any stipulation in lieu of a response should be jointly signed by yourself and the Division and filed within the time that a response would otherwise be due. Alternatively, any stipulation to resolve this case in lieu of the hearing shall be jointly signed by the parties and filed no later than one (1) week prior to the scheduled hearing.

Unless this case is resolved by a stipulation between the parties in lieu of the filing of a response, **a prehearing conference will be conducted as follows:**

June 25, 2019 at 11:00 A.M. by teleconference

During the conference, Judge Dibb will address and resolve any further discovery issues. A schedule for the filing of any prehearing motions shall also be established.

Subject to the Department of Commerce Administrative Procedures Act Rules which govern this proceeding, this formal adjudicative proceeding must be completed within 180 calendar days from the date of issuance of this notice of agency action.

You are entitled by law to an evidentiary hearing to determine whether your licenses to operate as a pharmacy and to dispense controlled substances in the State of Utah should be revoked, suspended or subjected to other disciplinary action. Unless otherwise specified by the Director of the Division, the Utah State Board of Pharmacy will serve as fact finder in the hearing. **The hearing will be conducted as follows:**

November 19, 2019 at 9:00 A.M. Room 403, Heber Wells Building

4th floor
160 East 300 South
Salt Lake City, Utah

During the evidentiary hearing, you will have the opportunity to present an opening statement, submit evidence, conduct cross-examination, submit rebuttal evidence and offer a closing statement to the fact finder. After the close of the hearing, the Board will take the matter under advisement and then submit its Findings of Fact, Conclusions of Law and a Recommended Order to the Division for its review and action.

Dated this 3 day of May, 2019.

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

By: _____
DEBORAH BLACKBURN
Presiding Officer for Issuance of Notice of Agency Action

KEVIN M. MCDONOUGH (USB No. 5109)
Assistant Attorney General
SEAN D. REYES (USB No. 7969)
Utah Attorney General
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BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING OF THE DEPARTMENT OF COMMERCE OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF **A & W PHARMACY,** UTAH LICENSE # 8932016-1703 AND UTAH LICENSE # 8932016-8913, TO OPERATE AS A PHARMACY AND TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	**PETITION** Case No. DOPL – 2019 - 189

PRELIMINARY STATEMENT

These claims were investigated by the Utah Division of Occupational and Professional Licensing (the "Division") upon complaints that A & W Pharmacy ("Respondent" or "A & W"), a licensee of the Division, has engaged in acts and practices which constitute violations of the Division of Occupational and Professional Licensing Act, Utah Code Ann. §§ 58-1-101 through 58-1-507 (2011); Utah's Pharmacy Practice Act, Utah Code Ann. §§ 58-17b-101 through 58-17b-907 (2016); Utah's Pharmacy Practice Act Rule, Utah Administrative Code R156-17b-101 through R156-17b-907(e) (2016); the Utah Controlled Substance Act, Utah Code Ann. §§ 58-37-1 through

58-37-18 (1971); and the Utah Controlled Substance Act Rule, Utah Administrative Code R156-37-101 through R156-37-608 (2016).

The allegations against Respondent in this Petition are based upon information and belief arising out of the Division's investigation. Each Count in this Petition shall be deemed to incorporate the allegations set forth in the other paragraphs of the Petition.

PARTIES

1. The Division is a division of the Department of Commerce of the State of Utah as established by Utah Code Ann. § 13-1-2 (2010).

2. At all times relevant to the material allegations set forth herein, Respondent was licensed by the Division as a class A retail pharmacy under Utah's Pharmacy Practice Act, Utah Code Ann. §§ 58-17b-101 through 58-17b-907(e) (2016). Respondent was also licensed to dispense controlled substances under the Utah Controlled Substance Act, Utah Code Ann. §§ 58-37-1 through 58-37-18 (1971).

STATEMENT OF ALLEGATIONS

3. On or about February 6, 2014, Respondent became licensed by the Division to operate as a Class A retail pharmacy and to dispense controlled substances in the State of Utah. Respondent's license permitted it to conduct business as a Class A retail pharmacy at 171 East Main Street in Duchesne, Utah 84021.

4. On May 12, 2016, the Division conducted a random inspection of A & W Pharmacy at the location set forth in Paragraph No. 3 above ("random inspection"). At the time of the random inspection, Respondent was a "compounding facility" engaged in simple, moderate or complex non-sterile compounding activities, and as such, was required to maintain proper records

and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. Accordingly, the single random inspection was dichotomized into a "Class A Retail Pharmacy Inspection" and a "Non-Sterile Compounding Inspection." Wade Poulson was Respondent's pharmacist-in-charge ("PIC") at the time and he assisted with the random inspection.

5. At the time of the random inspection, Respondent's regular inventory included a total of twenty-two (22) bottles of expired/indeterminate medications; eight (8) of the medications were expired and fourteen (14) had no expiration date assigned.

6. At the time of the random inspection, Respondent failed to separately maintain records for active pharmaceutical ingredient ("API") controlled substances from records of regular legend API drugs.

7. During the random inspection, in reviewing the annual controlled substance inventories, the Division discovered that the inventories for the years 2014 and 2015 failed to indicate the time that the inventory was taken.

8. During the random inspection, the Division examined invoices that Respondent had received from its suppliers for API controlled substances. A review of the invoices reflects that neither a pharmacist nor any other responsible individual signed invoices verifying receipt of controlled substances.

9. During the random inspection, the Division discovered that Respondent was engaging in compounding items that are regularly and commonly available directly from a manufacturer. More specifically, Respondent was compounding Acetazolamide 500 mg. capsules, Hydrocortisone 25 mg. susp. and Sucralfate 100 mg./ml supp. Respondent was engaging in such

compounding without having any documentation referencing a medically necessary reason for doing so.

10. All significant procedures performed in the compounding area of a Class A pharmacy should be covered by written standard operating procedures ("SOP's") which establish procedural consistency and also provide a reference for orientation and training of personnel. During the random inspection, the Division discovered that Respondent's SOP's failed to address its facility, equipment, and storage of materials.

11. During the random inspection, the Division discovered multiple API controlled substances that did not reflect a manufacturer's assigned expiration date, nor were the containers labeled with the date of receipt and/or an assigned "beyond use date" not to exceed three years.

12. During the random inspection, the Division discovered that Respondent was using distilled water for purposes of rinsing equipment and utensils. Purified water should be used for rinsing equipment and utensils.

13. During the random inspection, the Division noted that compounding personnel were not evaluated annually.

14. During the random inspection, the Division discovered that not all of Respondent's employees involved in pharmaceutical compounding were familiar with *United States Pharmacopeia – National Formulary,* Chapter 795 ("USP-NF Chapter 795").

15. At the time of the random inspection, the Division discovered that not all employees had read and were familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing (consistent with USP-NF Chapter 795-*Training*).

16. At the time of the random inspection, the Division discovered that Respondent had failed to develop and/or complete "master worksheets" for each batch of non-sterile pharmaceuticals to be prepared. More specifically, Respondent's records failed to reflect the following minimally required information: calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients; storage requirements; compatibility and stability information; description of final preparation; container used in dispensing; and quality control procedures and expected results.

17. At the time of the random inspection, the Division discovered that Respondent had failed to develop and/or complete "compounding preparation sheets" for each batch of non-sterile pharmaceuticals to be prepared. More specifically, Respondent's records failed to reflect the following minimally required information: names, initials, or electronic signature of the person involved in the preparation; name of the person who performed the quality control procedures; documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver; calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients; storage requirements; and results of quality control procedures.

18. On November 14, 2018, the Division conducted another random inspection of A & W Pharmacy at the location set forth in Paragraph No. 3 above ("2018 random inspection"). The 2018 random inspection was compartmentalized into three segments, (i) Class A Retail Pharmacy Inspection; (ii) Non-Sterile Compounding Inspection; and (iii) Automated Pharmacy System Inspection. Wade Poulson was Respondent's PIC at the time of the 2018 random inspection and he assisted with the same.

19. At the time of the 2018 random inspection, Respondent did not have a readily available, current list of its licensed pharmacy employees.

20. At the time of the 2018 random inspection, there was at least one employee who was not wearing a clearly visible and readable identification showing the individual's name and position.

21. During the 2018 random inspection, a review of records indicated that Respondent had failed to record the temperature of the pharmacy's refrigerator for the three previous days that the pharmacy was open.

22. During the 2018 random inspection, the Division determined that Respondent was failing to provide patients with required drug information sheets when it delivered refills of prescription drugs. Additionally, when mailing prescriptions to patients residing outside of the pharmacy's telephone area code, Respondent was failing to send a written statement advising the patient to read the drug information sheet before taking the medication and to call the pharmacy if the patient had any questions about the prescription.

23. During the 2018 random inspection, the Division examined Respondent's practices relative to mailing prescriptions to patients. The Division found that Respondent's SOP's for mailing prescriptions failed to fully address how to ensure accountability, safe delivery, and compliance with temperature requirements. The SOP's also failed to address what should occur when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. Additionally, Respondent was failing to provide information to patients indicating what a patient should do if the integrity of the packaging or drug was compromised during shipment.

24. During the 2018 random inspection, the Division found a compounded preparation of "Magic Mouthwash" bearing a prescription label with a "beyond use date" of greater than one month.

25. All significant procedures performed in the compounding area of a Class A pharmacy should be covered by written SOP's which establish procedural consistency and also provide a reference for orientation and training of personnel. During the 2018 random inspection, the Division discovered that Respondent's SOP's failed to address its facility, personnel, and storage.

26. During 2018 random inspection, the Division discovered one compounding ingredient that did not reflect a manufacturer's assigned expiration date, nor was the container labeled with the date of receipt and/or an assigned "beyond use date" not to exceed three years.

27. During the 2018 random inspection, the Division found containers with compounding components being stored on the floor.

28. During the 2018 random inspection, Respondent was not able to produce any documented training of compounding staff relative to storing, preparing, handling, cleaning, or disposal of hazardous drugs.

29. During the 2018 random inspection, the Division found that, although compounding staff had reviewed USP-NF Chapter 795 in 2018, there was no documentation of such a review for previous years.

30. During the 2018 random inspection, Respondent was not able to produce any documentation that reflected its compounding employees had reviewed or were familiar with A & W's non-sterile compounding SOP's.

31. During the 2018 random inspection, the Division discovered that Respondent's "Master Formulation Records" (sometimes referred to as a "master worksheets") were missing the following minimally required information: compatibility and stability information including references; the container used in dispensing; and packaging and storage requirements (especially related to shipping).

32. During the 2018 random inspection, the Division discovered that the "Compounding Records" were missing the name of the individual who performed the quality control procedures.

33. For each batch of sterile or non-sterile pharmaceuticals prepared by a pharmacy, there must be a label bearing minimum information, including "all active solution and ingredient names, amounts, strengths and concentrations, when applicable." During the 2018 random inspection, the Division discovered that some batch labels failed to include the name of all active ingredients.

34. All prescriptions for compounded sterile and non-sterile medications must have a label bearing minimum information, including the "generic name and quantity or concentration of each active ingredient." During the 2018 random inspection, the Division discovered that some prescription labels failed to identify all active ingredients by listing proprietary names.

35. Regarding the "Automated Pharmacy System" segment of the 2018 random inspection, the Division found that Respondent did not have documented policies and procedures in place addressing the safety, accuracy, and training of personnel relative to A & W's equipment on the premises.

36. Regarding the "Automated Pharmacy System" segment of the 2018 random inspection, the Division found that Respondent did not have documented policies and procedures in place that provided a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system. The Division also found that Respondent did not have documented policies and procedures in place that provided a mechanism for securing and accounting for medications that are wasted or discarded.

APPLICABLE LAW/RULES

37. **Utah Code Ann. § 58-1-401(2)(a) and (b)** gives the Division the legal authority to "revoke, suspend, restrict, place on probation, issue a public or private reprimand to, or otherwise act upon the license of a licensee" if the licensee "has engaged in unprofessional [or unlawful] conduct, as defined by statute or rule under this title[.]" Accord Utah Code Ann. § 58-63-401; Utah Administrative Code R156-1-102(7).

38. **Utah Code Ann. § 58-1-501(2)(a)** defines "unprofessional conduct" to include:

> violating, or aiding or abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title[.]

39. **Utah Code Ann. § 58-1-501(2)(b)** defines "unprofessional conduct" to include:

> violating, or aiding or abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession regulated under this title[.]

40. **Utah Code Ann. § 58-17b-302** sets forth in pertinent part:

> **58-17b-302 License required - - License classifications for pharmacy facilities.**
>
> . . .
>
> (6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall

be responsible for all activities of the pharmacy, regardless of the form of the business organization.

41. **Utah Code Ann. § 58-17b-502(1)** defines "unprofessional conduct" to include:

> (g) violating:
> (i) the federal Controlled Substances Act, Title II, P.L. 91-513;
> (ii) Title 58, Chapter 37, Utah Controlled Substances Act; or
> (iii) rules or regulations adopted under either act;
>
> . . .
>
> (m) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner;

42. **Utah Code Ann. § 58-17b-602** sets forth in pertinent part:

> **58-17b-602 Prescription orders - - Information required - - Alteration - - Labels - - Signatures - - Dispensing in pharmacies.**
> (5)
> (a) Each drug dispensed shall have a label securely affixed to the container indicating the following minimum information:
> (i) the name, address, and telephone number of the pharmacy;
> (ii) the serial number of the prescription as assigned by the dispensing pharmacy;
> (iii) the filling date of the prescription or its last dispensing date;
> (iv) the name of the patient, or in the case of an animal, the name of the owner and species of the animal;
> (v) the name of the prescriber;
> (vi) the directions for use and cautionary statements, if any, which are contained in the prescription order or are needed;
> (vii) except as provided in Subsection (7), the trade, generic, or chemical name, amount dispensed and the strength of dosage form, but if multiple ingredient products with establish proprietary or nonproprietary names are prescribed, those products' names may be used; and
> (viii) the beyond use date.

43. **Utah Code Ann. § 58-17-613** sets forth in pertinent part:

58-17b-613 Patient counseling.

. . .

(2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery, shall:

(a) provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses; and

(b) provide each patient with a toll-free telephone number by which the patient can contact a pharmacist or pharmacy intern at the pharmacy for counseling.

44. **Utah Administrative Code R156-17b-502** defines "unprofessional conduct" to include:

(1) violating any provision of the American Pharmaceutical Association (AphA) Code of Ethics for Pharmacists, October 27, 1994, which is hereby incorporated by reference;

. . .

(6) failing to abide by all applicable federal and state law regarding the practice of pharmacy;

. . .

(9) violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division;

. . .

(14) failing to offer to counsel any person receiving a prescription medication;

45. **Utah Administrative Code R156-17b-605** sets forth in pertinent part:

R156-17b-605. Operating Standards – Inventory Requirements.

(1) All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label.

(2) General requirements for inventory of a pharmacy shall include the following:

(a) the PIC or DMPIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

(b) the inventory records shall be maintained for a period of five years and be readily available for inspection;
(c) The inventory records shall be filed separately from all other records;

. . .

(e) the inventory may be taken either as the opening of the business or the close of business on the inventory date;
(f) the person taking the inventory and the PIC or DMPIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC or DMPIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;

. . .

(j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

46. **Utah Administrative Code R156-17b-608. Common Carrier Delivery.**

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, DMPIC, or other responsible employee:

. . .

(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs;

. . .

(5) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

47. **Utah Administrative Code R156-17b-610** sets forth in pertinent part:

R156-17b-610. Operating Standards – Patient Counseling.
In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

. . .

(3) Based upon the professional judgment of the pharmacist, pharmacy intern, or DMP, patient counseling may include the following elements:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) intended use of the drug, when known, and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

. . .

(6) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:

(a) the information specified in Subsection (3) of this section shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about his prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

(c) written information provided in Subsection (6)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

48. **Utah Administrative Code R156-17b-614a** sets forth in pertinent part:

R156-17b-614a. Operating Standards – General Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B pharmacies. The general operating standards include:

. . .

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare[.]

. . .

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) Facilities shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations.

. . .

(e) a master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record from which each batch is prepared and on which all documentation for that batch occurs. The master formulation record may be stored electronically and shall contain at a minimum:

(i) official or assigned name;
(ii) strength;
(iii) dosage form of the preparation;
(iv) calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;
(v) description of all ingredients and their quantities;

(vi) compatibility and stability information, including references when available;
(vii) equipment needed to prepare the preparation;
(viii) mixing instructions, which shall include:
(A) order of mixing;
(B) mixing temperature and other environmental controls;
(C) duration of mixing; and
(D) other factors pertinent to the replication of the preparation as compounded;
(ix) sample labeling information, which shall contain, in addition to legally required information:
(A) generic name and concentration of each active ingredient;
(B) assigned beyond use date;
(C) storage conditions; and
(D) prescription or control number, whichever is applicable;
(x) container used in dispensing;
(xi) packaging and storage requirements;
(xii) description of final preparation; and
(xiii) quality control procedures and expected results.

(f) A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:
(i) official or assigned name;
(ii) strength and dosage of the preparation;
(iii) Master Formulation Record reference for the preparation;
(iv) names and quantities of all components;
(v) sources, lot numbers, and expiration dates of components;
(vi) total quantity compounded;
(vii) name of the person who prepared the preparation;
(viii) name of the compounder who approved the preparation;
(ix) name of the person who performed the quality control procedures;
(x) date of preparation;
(xi) assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;
(xii) duplicate label as described in the Master Formulation Record means the sample labeling information that is dispenses on the final product given to the patient and shall at minimum contain:
(A) active ingredients;
(B) beyond-use-date;
(C) storage conditions; and
(D) lot number;

(xiv) proof of the duplicate labeling information, which proof shall:

(A) be kept at the pharmacy;
(B) be immediately retrievable;
(C) include an audit trail for any altered form; and
(D) be reproduce in:
(I) the original format that was dispensed;
(II) an electronic format; or
(III) a scanned electronic version;

(xvii) description of final preparation;
(xviii) results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
(xix) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

(g) The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

. . .

(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;

. . .

(h) All prescription labels for compound sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in Section 58-17b-602 the following:

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;

. . .

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

. . .

(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

49. **Utah Administrative Code R156-17b-620** sets forth in pertinent part:

R156-17b-620. Operating Standards – Automated Pharmacy System. In accordance with Section 58-17b-621, automated pharmacy systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Division and licensed health care facilities where legally permissible and shall comply with the following provisions:

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures and location shall be maintained on site in the pharmacy for review upon request of the Division. Such documentation shall include:

. . .

(e) policies and procedure for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.

. . .

(4) Automated pharmacy systems shall have:

. . .

(b) written policies and procedure in place prior to instillation to ensure safety, security, accuracy, training of personnel, and patient confidentiality and to define access and limits to access to equipment and medications.

. . .

(12) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system remain unused and must be secured and accounted for.

(13) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law. Written policies and procedures shall address situations in which medication removed from the system are wasted or discarded and must be secured.

50. **Utah Administrative Code R156-37-502** defines "unprofessional conduct" to include:

(2) violating any federal or state law relating to controlled substances;

. . .

(4) failing to maintain controls over controlled substances that would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances;

(5) being unable to account for shortages of any controlled substance inventory for which the licensee has responsibility;

. . .

(8) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so[.]

51. **Utah Administrative Code R156-37-602** sets forth in pertinent part:

R156-37-602. Records.

. . .

(3) all records required by federal and state laws or rules must be maintained by the licensee for a period of five years. If a licensee should sell or transfer ownership of records in any way, those records shall be maintained separately from other records of the new owner.

. . .

(6) All records relating to Schedules III, IV, and V controlled substances received, purchased, administered, or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice.

52. **Utah Administrative Code R156-17b-402** sets forth in pertinent part:

R156-17b-402. Administrative Penalties.

In accordance with Subsection 58-17b-401(6) and Sections 58-17b-501 and 58-17b-502, unless otherwise ordered by the presiding officer, the following fine and citation schedule shall apply:

. . .

(20) violating Federal title 11, PL91, Controlled Substances Act or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and regulations adopted under either act, in violation of Subsection 58-17b-502(7):

initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000

. . .

(34) failing to abide by all applicable federal and state law regarding the practice of pharmacy, in violation of Subsection R156-17b-502(6):

initial offense: $500 - $1,000
subsequent offense(s): $2,000 - $10,000

. . .

(37) violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division, in violation of Subsection r156-17b-502(9):

initial violation: $50 - $100
failure to comply within determined time: $250 - $500

subsequent violations: $250 - $500
failure to comply within established time: $750 - $1,000

. . .

(42) failing to offer to counsel any person receiving a prescription medication, in violation of Subsection R156-17b-502(14):
Pharmacy personnel initial offense: $500 - $2,500
Pharmacy personnel subsequent offense(s): $5,000 - $10,000
Pharmacy: $2,000 per occurrence

. . .

(58) violating or aiding or abetting any other person to violate any statute, rule or order regulating pharmacy, in violation of Subsection 58-1-501(2)(a):
initial offense: $100 - $2,000
subsequent offense(s): $2,000 - $10,000

. . .

(80) violating any federal or state law relating to controlled substances, in violation of Subsection R156-37-502(2):
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000

. . .

(82) failing to maintain controls over controlled substances that would be considered by a prudent licensee to be effective against diversion, theft, or shortage of controlled substances, in violation of Subsection R156-37-502(4):
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000

. . .

(86) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so, in violation of Subsection R156-37-502(8):
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000

COUNTS I THROUGH XXII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – INVENTORY REQUIREMENTS
(Failure to Remove Expired/Indeterminate Medications from Inventory)

53. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

54. As described in paragraph 5 hereinabove, at the time of the random inspection on May 12, 2016, Respondent's inventory included a total of twenty-two (22) expired/indeterminate medications; eight (8) of the medications were expired and fourteen (14) of had no expiration date assigned. This failure to remove out-of-date inventory violates Utah Administrative Code, R156-17b-605(1), which addresses operating standards – inventory requirements ("[a]ll out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use dated imprinted on the label"). Accordingly, Respondent's violation(s) of Utah Administrative Code R156-17b-605(1) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

55. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS XXIII THROUGH XLIV

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Remove Expired/Indeterminate Medications from Inventory)

56. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

57. As described in paragraph 5 hereinabove, at the time of the random inspection on May 12, 2016, Respondent's inventory included a total of twenty-two (22) expired/indeterminate medications; eight (8) of the medications were expired and fourteen (14) of had no expiration date assigned. Maintaining a stock of medications that is out-of-date poses a danger to the public health, safety and welfare, and therefore violates Utah Administrative Code, R156-17b-614a(1)(e), which addresses general operating standards for the practice of pharmacy (a class A pharmacy shall "be stocked with the quality and quantity of product necessary to for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare[.]" Accordingly, Respondent's violation(s) of Utah Administrative Code R156-17b-614a(1)(e) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

58. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT XLV

UNPROFESSIONAL CONDUCT: FAILURE TO SEGREGATE SCHEDULE III, IV, AND V CONTROLLED SUBSTANCES RECORDS FROM OTHER PHARMACY RECORDS

59. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

60. As stated in paragraph 6 hereinabove, Respondent failed to separately maintain records for API controlled substances from records of regular legend API drugs. Respondent's failure to properly segregate the files violates Utah Administrative Code R156-37-602(6) ("[a]ll records relating to Schedule III, IV, V controlled substances . . . shall be maintained separately from all other records of the pharmacy or practice"). Accordingly, Respondent's violation of Utah Administrative Code R156-37-602(6) constitute unprofessional conduct pursuant to Utah Administrative Code R156-37-502(2) ("violating any federal or state law relating to controlled substances") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

61. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS XLVI AND XLVII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – INVENTORY REQUIREMENTS
(Failure of Pharmacist-in-Charge to Date the Annual Controlled Substance Inventory)

62. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

63. As described in paragraph 7 hereinabove, during the random inspection, in reviewing the annual controlled substance inventories, the Division discovered that the inventories for the years 2014 and 2015 failed to indicate the time that the respective inventories were taken. Respondent's failure to appropriately document/verify the inventory violates Utah Administrative Code R156-17b-605(2)(f) ("the person taking the inventory and the PIC or DMPIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-605(2)(f) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division"), Utah Administrative Code R156-37-502(2) ("violating any federal or state law relating to controlled substances"), and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

64. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT XLVIII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – GENERAL OPERATING STANDARDS
(Failure to Verify Controlled Substances Listed on the Suppliers' Invoice Were Received)

65. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

66. As set forth in paragraph 8, during the random inspection, the Division examined invoices that Respondent had received from its suppliers for API controlled substances. A review of the invoices reflects that neither a pharmacist nor any other responsible individual had signed invoices for receipt of controlled substances. Respondent's failure to sign and date invoices for controlled substances received violates Utah Administrative Code R156-17b-614a(12) ("[a] pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(12) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division"), Utah Administrative Code R156-37-502(2) ("violating any federal or state law relating to controlled substances"), and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

67. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS XLIX THROUGH LI

UNPROFESSIONAL CONDUCT: INAPPROPRIATELY COMPOUNDING PRESCRIPTION DRUGS

68. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

69. As set forth in paragraph 9, Respondent compounded at least three (3) items (Acetazolamide; Hydrocortisone; and Sucralfate) that are regularly and commonly available directly from a manufacturer. Engaging in such compounding constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-17b-502(1)(m) ("[u]nprofessional conduct includes . . . compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner"). Accordingly, Respondent's violation of Utah Code Ann. § 58-17b-502(1)(m) also constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

70. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Maintain Standard Operating Procedures)

71. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

72. As set forth in paragraph 10, Respondent's standard operating procedures failed to address its facility, equipment, and storage of materials. USP-NF Chapter 795 sets forth, in part, that "all significant procedures performed in the compounding area should be covered by written operating procedures," including procedures relative to the "facility," "equipment," and "storage." Respondent's failure to have SOP's in place for its facility, equipment, and storage of materials, violates Utah Administrative Code R156-17b-614a(3)(a) ("[f]acilities engaged in simple, moderate or complex non-sterile. . . compounding activities shall be required to maintain proper records and procedure manuals[.] Facilities shall follow USP-NF Chapter 795, compounding of non-sterile preparations"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(a) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

73. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LIII

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure to Properly Label Controlled Substance Containers)

74. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

75. As set forth in paragraph 11, during the random inspection, the Division discovered multiple API controlled substances that did not reflect a manufacturer's assigned expiration date, nor were the containers labeled with the date of receipt and/or an assigned "beyond use date" not to exceed three years. USP-NF Chapter 795 – *Component Selection, Handling, and Storage*, sets forth, in part, that "[f]or components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt[.]" Respondent's failure to affix labels to controlled substance containers indicating the date upon which the controlled substance was received, violates a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

76. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LIV

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure to Rinse Equipment and Utensils with Purified Water)

77. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

78. As set forth in paragraph 12, Respondent used distilled water for purposes of rinsing equipment and utensils (rather than using purified water). USP-NF Chapter 795 – *Compounding Facilities,* sets forth, in part, that "*Purified Water* should be used for rinsing equipment and utensils." Respondent's failure to use purified water when rinsing equipment and utensils violates a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

79. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LV

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure to Appropriately Train and Evaluate Personnel Annually)

80. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

81. As set forth in paragraph 13, Respondent's compounding personnel were not evaluated annually. USP-NF Chapter 795 – *Responsibilities of the Compounder – General Principles of Compounding (1), Training,* provides that pharmacy personnel should be appropriately trained such that they are capable of performing and qualified to perform their assigned duties. To this end, USP-NF Chapter 795 sets forth, in part, that "[s]uch training should be documented [and] [c]ompounding personnel should be evaluated annually." Respondent's failure to evaluate its compounding personnel annually violates a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

82. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LVI

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure of Pharmacy's Compounding Personnel to be Familiar with USP-NF Chapter 795)

83. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

84. As set forth in paragraph 14, some of Respondent's employees who were involved in pharmaceutical compounding were not familiar with USP-NF Chapter 795. USP-NF Chapter 795 – *Training,* sets forth, in part, that "[a]ll employees involved in pharmaceutical compounding shall read and become familiar with [this Chapter 795]." Because some of Respondent's employees who were involved in pharmaceutical compounding were not familiar with USP-NF Chapter 795, Respondent has violated a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

85. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LVII

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure to be Familiar with Procedures Related to Compounding)

86. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

87. As set forth in paragraph 15, some of Respondent's employees had not read, nor were they familiar with, each of the procedures related to compounding. USP-NF Chapter 795 – *Training*, sets forth, in part, that "[a]ll employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing." Respondent's failure to ensure that its employees were familiar with each of the procedures related to compounding violates a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

88. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LVIII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Develop and/or Complete Master Worksheets)

89. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

90. As set forth in paragraph 16, Respondent failed to develop and/or complete "master worksheets" for each batch of non-sterile pharmaceuticals to be prepared. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(e) (formerly Utah Administrative Code, R156-17b-614a(3)(d)), which addresses general operating standards for the practice of pharmacy and requires facilities engaged in non-sterile compounding to maintain certain records and procedure manuals and establish quality control standards ("[a] master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. . . . The master formulation record may be stored electronically and shall contain [at a minimum, specified information.]") Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(e) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

91. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LIX

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Develop and/or Complete Compounding Preparation Sheets)

92. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

93. As set forth in paragraph 17, Respondent had failed to develop and/or complete "compounding preparation sheets" for each batch of sterile or non-sterile pharmaceuticals to be prepared. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(f) (formerly Utah Administrative Code, R156-17b-614a(3)(e)), which addresses general operating standards for the practice of pharmacy and requires facilities engaged in non-sterile compounding to maintain certain records and procedure manuals and establish quality control standards ("[a] compounding record for each batch of sterile or non-sterile pharmaceuticals shall document [at a minimum, specified information]"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(f) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

94. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LX

UNPROFESSIONAL CONDUCT:
VIOLATION OF PRACTICE OF PHARMACY - GENERAL OPERATING STANDARDS
(Failure to Maintain Current List of Licensed Employees)

95. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

96. As set forth in paragraph 19, at the time of the 2018 random inspection, Respondent did not have a readily available, current list of its licensed pharmacy employees. This failure to maintain such a list violates Utah Administrative Code, R156-17b-614a(5), which addresses general operating standards for Class A and B pharmacies ("[t]he facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility [and] [t]he list shall be readily retrievable"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(5) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

97. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXI

UNPROFESSIONAL CONDUCT:
VIOLATION OF PRACTICE OF PHARMACY - OPERATING STANDARDS
(Failure to Appropriately Display Employee Identification)

98. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

99. As set forth in paragraph 20, at the time of the 2018 random inspection, there was at least one employee failing to wear a clearly visible and readable identification showing the individual's name and position. This failure to appropriately display identification violates Utah Code Ann. § 58-17b-603(1) ("[a]ll individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility shall wear on their person a clearly visible and readable identification showing the individuals name and position"). Accordingly, Respondent's violation of Utah Code Ann. § 58-17b-603(1) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

100. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXII

UNPROFESSIONAL CONDUCT:
VIOLATION OF PRACTICE OF PHARMACY - GENERAL OPERATING STANDARDS
(Failure to Keep a Daily Log of the Temperature of the Pharmacy's Refrigerator)

101. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

102. As set forth in paragraph 21, during the 2018 random inspection, a review of records indicated that Respondent had failed to record the temperature of the pharmacy's refrigerator for the three previous days that the pharmacy was open. This failure to record the temperature of the refrigerator violates Utah Administrative Code, R156-17b-614a(2) ("[i]f a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on the days of operation"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(2) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

103. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXIII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – PATIENT COUNSELING
(Failure to Provide Written Monographs with the Delivery of Dispensed Prescriptions)

104. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

105. As set forth in paragraph 22, Respondent failed to provide patients with required drug information sheets when it delivered refills of prescription drugs. Additionally, when mailing prescriptions to patients residing outside of the pharmacy's telephone area code, Respondent failed to send a written statement advising the patient to read the drug information sheet before taking the medication and to call the pharmacy if the patient had any questions about the prescription. Respondent's failure to provide the written information with the delivery of dispensed prescriptions violates Utah Administrative Code R156-17b-610(6)(a) ("[i]f a prescription drug order is delivered to the patient . . . the information specified in Subsection (3) of this section shall be delivered with the dispensed prescription in writing") and Utah Administrative Code R156-17b-610(6)(b). Accordingly, Respondent's violations of Utah Administrative Code R156-17b-610(6)(a) and (b) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

106. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS LXIV AND LXV

UNPROFESSIONAL CONDUCT: FAILURE TO DEVELOP AND IMPLEMENT POLICES AND PROCEDURES WHEN DELIVERING PRESCRIPTIONS BY COMMON CARRIER

107. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

108. As set forth in paragraph 23, Respondent's SOP's for mailing prescriptions failed to fully address how to ensure accountability, safe delivery, and compliance with temperature requirements. The SOP's also failed to address what should occur when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. Additionally, Respondent was failing to provide information to patients indicating what a patient should do if the integrity of the packaging or drug was compromised during shipment. These failures by Respondent violate Utah Administrative Code R156-17b-608(3) and (5) ("[a] pharmacy that employs the United States Postal Service or other common carrier to deliver filled prescriptions directly to a patient shall . . . develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment . . . [A pharmacy shall] provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised

during shipment"). Accordingly, Respondent's violations of Utah Administrative Code R156-17b-608(3) and (5) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

109. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXVI

UNPROFESSIONAL CONDUCT: VIOLATION OF OPERATING STANDARDS – PRESCRIPTION DRUG LABEL (Incorrect "Beyond Use Date")

110. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

111. As set forth in paragraph 24, Respondent's inventory included a compounded preparation of "Magic Mouthwash" bearing a prescription label with a "beyond use date" of greater than one month; the compound in issue is not to be used beyond one month of the compounding of the medication. Maintaining inventory with such incorrect labeling violates Utah Code Ann. § 58-17b-602(5)(viii) ("[e]ach drug dispensed shall have a label securely affixed to the container indicating the [correct] beyond use date"). Accordingly, Respondent's violation of Utah Code Ann. § 58-17b-602(5)(viii) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy

discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

112. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXVII

UNPROFESSIONAL CONDUCT: VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS (Failure to Maintain Standard Operating Procedures)

113. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

114. As set forth in paragraph 25, during the 2018 random inspection, the Division discovered that Respondent's standard operating procedures failed to address its facility, personnel, and storage. USP-NF Chapter 795 sets forth, in part, that "all significant procedures performed in the compounding area should be covered by written operating procedures," including procedures relative to the "facility," "personnel," and "storage." Respondent's failure to have SOP's in place for its facility, personnel, and storage of materials, violates Utah Administrative Code R156-17b-614a(3)(a) ("[f]acilities engaged in simple, moderate or complex non-sterile. . . compounding activities shall be required to maintain proper records and procedure manuals[.] Facilities shall follow USP-NF Chapter 795, compounding of non-sterile preparations"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(a) constitutes

unprofessional conduct pursuant to Utah Administrative Code R156-17-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

115. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXVIII

UNPROFESSIONAL CONDUCT: VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD (Failure to Properly Label Controlled Substance Container)

116. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

117. As set forth in paragraph 26, during 2018 random inspection, the Division discovered one compounding ingredient that did not reflect a manufacturer's assigned expiration date, nor was the container labeled with the date of receipt and/or an assigned "beyond use date" not to exceed three years. USP-NF Chapter 795 – *Component Selection, Handling, and Storage*, sets forth, in part, that "[f]or components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt[.]" Respondent's failure to affix a label to the controlled substance container indicating the date upon which the controlled substance was received, violates a standard set forth in USP-NF Chapter 795.

Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

118. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXIX

UNPROFESSIONAL CONDUCT: VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD (Containers with Compounding Components Being Stored on the Floor)

119. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

120. As set forth in paragraph 27, during the 2018 random inspection, the Division found containers with compounding components being stored on the floor. USP-NF Chapter 795 – *Packaging and Drug Preparation Containers*, sets forth, in part, that pharmaceutical "containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the older stock is used first." By storing the containers on the floor, Respondent has violated a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

121. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS LXX AND LXX1

UNPROFESSIONAL CONDUCT: VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD (Failure to Appropriately Train Personnel Working with Hazardous Drugs)

122. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

123. As set forth in paragraph 28, during the 2018 random inspection, Respondent was not able to produce any documented training of compounding staff relative to storing, preparing, handling, cleaning, or disposal of hazardous drugs. USP-NF Chapter 795-*Compounding Facilities,* sets forth, in part, that "[h]azardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel [and] [a]ll personnel who perform routine custodial waste removal and cleaning activities in storage areas for hazardous drugs shall be trained in appropriate procedure to protect themselves and prevent contamination." By failing to have its compounding staff appropriately trained, Respondent has violated a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

124. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXII

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure of Pharmacy's Compounding Personnel to be Familiar with USP-NF Chapter 795)

125. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

126. As set forth in paragraph 29, during the 2018 random inspection, the Division found that, although compounding staff had reviewed USP-NF Chapter 795 in 2018, there was no documentation of such a review for previous years. USP-NF Chapter 795 – *Training,* sets forth, in part, that "[a]ll employees involved in pharmaceutical compounding shall read and become familiar with [this Chapter 795]." There being no documented evidence that Respondent's employees, prior to 2018, had reviewed USP-NF Chapter 795, Respondent has violated a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

127. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXIII

UNPROFESSIONAL CONDUCT:
VIOLATION OF GENERALLY ACCEPTED PROFESSIONAL STANDARD
(Failure to be Familiar with Procedures Related to Compounding)

128. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

129. As set forth in paragraph 30, during the 2018 random inspection, Respondent was not able to produce any documentation that reflected its compounding employees had reviewed or were familiar with A & W's non-sterile compounding SOP's. USP-NF Chapter 795 – *Training*, sets forth, in part, that "[a]ll employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing." Respondent's failure to ensure that its employees were familiar with each of the procedures related to compounding violates a standard set forth in USP-NF Chapter 795. Accordingly, Respondent's violation of the standard constitutes unprofessional conduct pursuant to Utah Code Ann. § 58-1-501(2)(b) ("violating, or aiding and abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession under this title").

130. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXIV

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Develop and/or Complete Master Formulation Records)

131. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

132. As set forth in paragraph 31, during the 2018 random inspection, the Division discovered that Respondent's "Master Formulation Records" (sometimes referred to as "master worksheets") failed to include the following minimally required information: compatibility and stability information; the container used in dispensing; and packaging and storage requirements. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(e) (formerly Utah Administrative Code, R156-17b-614a(3)(d)), which addresses general operating standards for the practice of pharmacy and requires facilities engaged in non-sterile compounding to maintain certain records and procedure manuals and establish quality control standards ("[a] master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. . . . The master formulation record may be stored electronically and shall contain at a minimum . . . compatibility and stability information, including references when available; . . . container used in dispensing; [and] packaging and storage requirements. Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(e) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and

abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

133. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXV

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Complete Compounding Record)

134. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

135. As set forth in paragraph 32, during the 2018 random inspection, the Division discovered that the "Compounding Record" failed to identify the individual who performed the quality control procedures. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(f)(ix) (formerly Utah Administrative Code, R156-17b-614a(3)(e)), which addresses general operating standards for the practice of pharmacy and requires a pharmacy to document specific information ("[a] compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the . . . name of the person who performed the quality control procedures"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(f) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and

abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

136. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXVI

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Properly Label Batches of Non-Sterile Pharmaceuticals)

137. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

138. As set forth in paragraph 33, during the 2018 random inspection, the Division found that some batches of non-sterile pharmaceuticals prepared by Respondent failed to bear labels which included required information. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(g)(ii), which addresses general operating standards for the practice of pharmacy ("[t]he label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum . . . all active solution and ingredient names, amounts, strengths and concentrations, when applicable"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(g)(ii) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

139. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNT LXXVII

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS - GENERAL OPERATING STANDARDS
(Failure to Properly Label Prescriptions of Non-Sterile Pharmaceuticals)

140. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

141. As set forth in paragraph 34, during the 2018 random inspection, the Division found that some prescriptions for compounded non-sterile medications failed to bear labels which included required information. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-614a(3)(h)(i), which addresses general operating standards for the practice of pharmacy ("[a]ll prescription labels for compounded sterile or non-sterile medications . . . shall bear at a minimum . . . [the] generic name and quantity or concentration of each active ingredient"). Accordingly, Respondent's violation of Utah Administrative Code R156-17b-614a(3)(h)(i) constitutes unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

142. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS LXXVIII AND LXXIX

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – AUTOMATED PHARMACY SYSTEM
(Failure to Have Documented Policies and Procedures Relative to Pharmacy Equipment)

143. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

144. As set forth in paragraph 35, Respondent failed to have documented policies and procedures in place addressing the safety, accuracy, and training of personnel relative to A & W's equipment on the premises. Respondent's failure in this regard violates Utah Administrative Code, R156-17b-620(1)(e), which addresses operating standards applicable to an automated pharmacy system ("[d]ocumentation as to the type of equipment . . . shall include . . . policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction"). Respondent's failure also violates Utah Administrative Code, R156-17b-620(4)(b), which further addresses operating standards applicable to an automated pharmacy system ("[a]utomated pharmacy systems shall have . . . written policies and procedures in place prior to installation to ensure safety, accuracy, security, training of personnel, and patient confidentiality to define access and limits to access to equipment and medications"). Accordingly, Respondent's violations of Utah Administrative Code R156-17b-620(1)(e) and (4)(b) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and

Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

145. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

COUNTS LXXX AND LXXXI

UNPROFESSIONAL CONDUCT:
VIOLATION OF OPERATING STANDARDS – AUTOMATED PHARMACY SYSTEM
(Failure to Have Documented Policies and Procedures that Provide a Mechanism for Securing and Accounting for Medications Removed from the System)

146. Paragraphs 1 through 52 are incorporated herein and by this reference made a part hereof.

147. As set forth in paragraph 36, Respondent failed to have documented policies and procedures in place that provided a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system; Respondent also failed to have documented policies and procedures in place that provided a mechanism for securing and accounting for medications that are wasted or discarded. Respondent's failures violate Utah Administrative Code, R156-17b-620(12) and (13), both of which address operating standards applicable to an automated pharmacy system ("[t]he automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system . . . Written policies and procedures shall address situations in which medications removed from the system remain unused and must be secured and accounted for"); ("[t]he automated pharmacy system shall provide a mechanism for securing and accounting

for wasted medications or discarded medications . . . Written policies and procedures shall address situations in which medications removed from the system are wasted or discarded and must be secured"). Accordingly, Respondent's violations of Utah Administrative Code R156-17b-620(12) and (13) constitute unprofessional conduct pursuant to Utah Administrative Code R156-17b-502(9) ("violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division") and Utah Code Ann. § 58-1-501(2)(a) ("violating, or aiding and abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title").

148. Respondent's unprofessional conduct gives the Division the legal authority to impose sanctions against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a); accord Utah Administrative Code R156-1-102(7).

WHEREFORE, the Division requests the following relief:

1. That Respondent be adjudged and decreed to have engaged in the acts alleged herein;

2. That by engaging in the above described acts, Respondent be adjudged and decreed to have violated provisions of the Division of Occupational and Professional Licensing Act;

3. That Respondent's licenses to practice as a pharmacy and to dispense controlled substances in the State of Utah be revoked, suspended or placed on probation; and

4. That an administrative fine in an amount of no less than $48,150.00 should be imposed upon Respondent.

Respectfully submitted this 30th day of April 2019.

UTAH ATTORNEY GENERAL
SEAN D. REYES

Kevin M. McDonough
Assistant Attorney General

VERIFICATION SHEET

STATE OF UTAH)
: ss
SALT LAKE COUNTY)

Sharilee McIntyre, being first duly sworn, states as follows:

1. I am a Pharmacy Inspector for the Division of Occupational and Professional Licensing (DOPL) and have been assigned to investigate this case.

2. I have read the foregoing Petition and am familiar with the contents thereof. All of the factual allegations in the Petition are true to the best of my knowledge, information and belief.

SHARILEE MCINTYRE
DOPL Inspector

SWORN TO AND SUBSCRIBED before me this 30 day of April, 2019.

NOTARY PUBLIC
COLLEEN GONZALEZ
Commission No. 699168
Commission Expires
FEBRUARY 26, 2022
STATE OF UTAH

Colleen Gonzalez
Notary Public